

### **REMARKS**

Claim 1-6 are pending and stand rejected. Claims 1-6 have been amended. Support for amended claims 1-6 can be found, for example, on page 9 line 9 through page 10 line 18.

With respect to all amendments and cancelled claims, Applicants have not dedicated or abandoned any unclaimed subject matter and moreover have not acquiesced to any rejections and/or objections made by the Patent Office. Applicants reserve the right to pursue prosecution of any presently excluded claim embodiments in future continuation and/or divisional applications.

#### **Abstract**

The abstract was objected as allegedly not adequately describing the claimed invention, as required under MPEP § 608.01(b). An amended abstract is included in the amendment to the specification. Applicants respectfully request entry of this amendment and withdrawal of this objection.

#### **Title**

The title was objected to as allegedly not descriptive. An amended title is included in the amendment to the specification. Applicants respectfully request entry of this amendment and withdrawal of this objection.

#### **Declaration under 37 C.F.R. § 1.132**

Applicant points out that a declaration by the inventor David A. Horwitz, executed August 19, 2006, accompanies this response.

#### **Rejection under 35 U.S.C. § 112, second paragraph**

Claims 1-6 stand rejected under 35 U.S.C. § 112 (second paragraph) as allegedly being incomplete for omitting essential steps. As currently amended, the claims recite PBMC comprising suppressor T cells. No essential step is required to isolate the recited suppressor T cells. Applicants request that this rejection be withdrawn.

**Rejection under 35 U.S.C. § 102**

Claims 1-3 and 6 stand rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by McIntosh et al., U.S. Patent No. 6,685,936 (hereinafter "McIntosh"). Claims 1-5 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Hall et. al. J. Exp. Med. 1990; 171: 141-157 (hereinafter "Hall"). Applicant respectfully traverses these rejection.

**I. The claimed suppressor T cells are different**

The Examiner has relied on Hall and McIntosh to reject the present claims as anticipated by asserting that although neither reference discloses the same process of making the suppressor T cells, the patentability of a product does not depend on its method of production. (See pages 3-4 of the Office Action). Applicant submits that the suppressor T cells produced by the claims methods differ from the cells disclosed in the references.

*A. Claimed cells do not require CD8+ cells for suppressive activity.*

As described in the accompanying declaration and Examples 1 and 3, the presently claimed suppressor T cells have been shown to exhibit suppressive activity independent of CD8+ cells.

*B. Suppressor T cells disclosed in the references require CD8+ cells for suppressive activity.*

In contrast, the suppressive activity of the suppressor T cells disclosed in the references is dependent on the presence of CD8+ cells. As described in paragraph 7 of the accompanying declaration, Hall discloses data showing graft rejection by CD8+ cell-depleted host animals compared to an absence of graft rejection in animals not depleted of CD8+ cells (Table V and page 148, first paragraph). Hall's "suppressor cells" therefore requires CD8+ cells in order to prevent graft rejection.

The suppressor T cells disclosed by McIntosh also require CD8+ cells. As discussed in paragraph 8 of the accompanying declaration, the pre-culturing of CD8+-depleted cells with

USSN: 10/772,768  
Filing Date: February 4, 2004

mesenchymal stem cells resulted in partial and delayed suppression of a mixed lymphocyte reaction (Fig. 2-3 and Col. 7, lines 38-41).

II. Hall and McIntosh do not anticipate the invention

The invention provides suppressor T cells that are not dependent on the presence of CD8+ cells in order to have suppressive activity. Hall and McIntosh disclose suppressor T cells that are dependent on CD8 in order to exhibit suppressive activity. As such, the cells of the invention are different from the cells disclosed in the reference. Applicants respectfully request the withdrawal of this rejection.

Acknowledgment of Applicant's Information Disclosure Statement submitted January 31, 2005

The Examiner has acknowledged receipt of Applicant's Information Disclosure Statement (IDS) filed on January 31, 2005. However, the Examiner has not considered References Nos. C7, C16, C24, C35, C44, C76, C78 and C126 of the IDS due to citation errors. Applicant will submit a corrected Information Disclosure Statement directed to these concerns at a later date to address this matter.

USSN: 10/772,768  
Filing Date: February 4, 2004

### CONCLUSION

Applicant respectfully submits that the claims are now in condition for allowance and early notification to that effect is respectfully requested. If the Examiner feels there are further unresolved issues, the Examiner is respectfully requested to phone the undersigned at (415) 781-1989.

Respectfully submitted,  
DORSEY & WHITNEY LLP

Dated: August 21, 2006  
Customer Number: 32940  
Dorsey & Whitney LLP  
555 California Street, Suite 1000  
San Francisco, CA 94104-1513  
Telephone: (415) 781-1989  
Facsimile: (415) 398-3249

BY: J.P. Bernhardt  
Jeffery P. Bernhardt, Reg. No. 54,997 for  
Richard F. Trecartin, Reg. No. 31,801

*Filed under 37 C.F.R. § 1.34*

4850-3043-5585\1